

Notice of Allowability

Application No.

10/091,559

Applicant(s)

OCHIAI ET AL.

Examiner

Art Unit

Humera N. Sheikh

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 13 October 2006.
2. ☒ The allowed claim(s) is/are 1 and 10.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of the:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

7. ☒ The Drawings filed 3/7/2002 are accepted by the Examiner.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material

5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment

8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

HUMERA N SHEIKH
PRIMARY EXAMINER

DETAILED ACTION

Status of the Application

Receipt of the Amendment after Final Office Action and Applicant's Arguments/Remarks, both filed 10/13/06 is acknowledged.

Claims 1 and 10 are pending in this action. Claims 2-9 and 11-14 have been cancelled.
Claims 1 and 10 are allowed.

EXAMINER'S AMENDMENT

The application has been amended as follows:

In the Claims:

In Claim 10, section (b), the first term "*a*" has been **deleted**.

Allowable Subject Matter

Claims 1 and 10 are allowed.

The following is an examiner's statement of reasons for allowance:

The primary reasons for allowance are that the prior art (Pierre *et al.* – U.S. Pat. No. 5,300,318 & Koyama *et al.* – U.S. Pat. No. 5,855,914) does not disclose nor fairly teach or suggest the presently claimed process for making a drug granule and a coated drug granule, whereby the drug granule has substantially higher granular strengths of 650-2500 gf/mm². The granules of the prior art do not have enough strength for tableting without substantial amount of

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binder. The instant method of manufacturing granules allows for granules to be subjected to a 'tableting' step without breakage of the granules. The prior art also does not disclose or teach such a process for making a drug granule and coated drug granule that achieves higher granular strengths (650-2500 gf/mm²) with respect to the drugs selected from the group consisting of metformin hydrochloride, ethydrone acid di-sodium, cimetidine carbocysteine, gabapentin, ciprofloxacin hydrochloride, mexiletine hydrochloride and vancomycin hydrochloride as currently claimed herein. The method of the instant invention is also distinguishable from the prior art (Pierre *et al.* '318) in that the instant invention method utilizes a 'rotary fluidized bed granulate coating apparatus', whereas, in contrast, Pierre *et al.* utilizes a Uniglatt apparatus (a non-rotary fluidized bed coating device).

The instant invention's method demonstrates an improvement over prior art formulation methods in that it allows for the manufacture of tablets from the coated granules having desirable and suitable dissolution characteristics. The instant invention also provides for unexpected results, such as a difference in resistance ability to acid solution. The instant method of manufacturing granules also allows for granules to be subjected to a 'tableting' step without breakage of the granules, due to higher granular strengths of 650-2500 gf/mm².

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

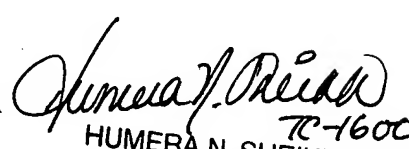
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Humera N. Sheikh

Primary Examiner

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October 30, 2006


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HUMERA N SHEIKH
PRIMARY EXAMINER

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